Evaluation Set-Aside Application

For projects over $50,000

Cancer Disparities Research Partnership (CDRP) Program Process and Outcome Evaluation

IC: National Cancer Institute Division of Cancer Treatment and Diagnosis
Radiation Research Program

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SECTION 1: Program to be Evaluated

1.1 Program Name

Cancer Disparities Research Partnership (CDRP) Program

1.2 Program Description

The Cancer Disparities Research Partnership (CDRP) Program is a 5-year U56 Cooperative Planning Grant being conducted by the Radiation Research Program (RRP) within the NCI's Division of Cancer Treatment and Diagnosis (DCTD). The overall goal of the CDRP Program is to reduce the significant negative consequences of cancer health disparities seen in certain U.S. populations. This goal is to be reached by building and stabilizing clinical trials research in radiation oncology in institutions that care for a disproportionate number of medically underserved, low-income, and racial and ethnic minority populations, but which have not traditionally been involved in NCI-sponsored research. The CDRP Program has four components: (1) planning, developing, and conducting radiation oncology clinical trials; (2) planning, developing, and implementing nurturing partnerships between grantee institutions and academic research institutions actively involved in NCI-sponsored cancer research; (3) establishing a compatible telemedicine system (TELESYNERGY®) at each CDRP grantee institution and its primary partner to augment the partnerships (see Exhibit 1); and (4) supporting a Patient Navigator to facilitate access to radiation oncology services, including clinical trials, by addressing barriers (e.g., financial, geographic, cultural) that impact timely cancer care delivery to patients from target populations.

Six institutions, new to clinical trials research, are involved in this CDRP Program. Two awards were made in 2002, and four additional awards were made in 2003. The CDRP Program runs until 2008 and has a total 5-year cumulative budget of $25 million. The six grantee sites and their service area populations are shown in Table 1 below.

Table 1 – CDRP Program Grantees and Service Area Population Numbers

Awardee	Service Area Population
Rapid City Regional Hospital, Rapid City, SD	300,000
Laredo Medical Center, Laredo, TX	177,000
Singing River Hospital, Pascagoula, MS	200,000
New Hanover Regional Medical Center, Wilmington, NC	616,000
UPMC McKeesport Hospital, McKeesport, PA	935,000
Daniel Freeman Memorial Hospital, Los Angeles, CA	100,000

1.3 Program Goals

The CDRP Program goals, which are all relevant to this proposed Evaluation, are:

Process Goals:

1. Publications about the CDRP Program by grantees and partners in peer-reviewed journals and presentations at national conferences (Program Components 1 to 4).
2. Increased numbers of clinical scientists engaged in radiation oncology clinical research (Program Components 1 & 2).
3. Increased numbers of patients from target populations participating in radiation oncology clinical trials (Program Components 1 & 4).
4. Increased collaborative research and clinical consultation between grantees and academic research partners (Program Component 2).
5. Frequent use of TELESYNERGY® to facilitate collaboration and consultation between grantees and academic research partners (Program Components 2 & 3).

6. Patient Navigators who decrease barriers to receipt of cancer care services and increase participation in clinical trials by targeted populations (Program Component 4).

Outcome Goals:

7. Develop a sustainable community-based radiation oncology clinical research model by increasing knowledge of and skill in conducting clinical research with targeted populations in community-based institutions (Program Components 1 to 4).
8. Increase radiation oncology research by community-based clinical researchers (Program Components 1 & 2).
9. Establish sustainable partnerships for cancer treatment and research between academic institutions and community-based clinical researchers (Program Component 2).
10. Effectively use the TELESYNERGY® telemedicine system to support clinical research and patient care (Program Component 3).
11. Improve patient care and participation of targeted populations in clinical trials through support from Patient Navigators (Program Components 1 & 4).

SECTION 2: Need for an Evaluation

2.1 Type of Evaluation

The RRP/DCTD proposes to conduct a 4-year evaluation that has process and outcome components.

2.2 Purpose of Evaluation

The purpose of this evaluation is to measure the relevance, effectiveness, and impact of the CDRP Program[1] in a consistent fashion so that findings can be applied in other settings and will produce meaningful annual reports to stakeholders of interest, both within and outside the NCI. RRP/DCTD has been funding CDRP grantees since 2002, with the awardees' having the goal of replacing CDRP grant funding by the end of the award performance period. A formal evaluation is needed to assess whether the projects are succeeding in accomplishing the goals stated in their grant applications and whether the CDRP Program as a whole is accomplishing its goals as put forth in the Request for Applications. The proposed Evaluation has both process and outcome questions.

This proposed evaluation study is the second phase of an evaluation project; the first phase (feasibility study) was supported by an Evaluation Express Award and successfully completed on September 16, 2005. The focus of the Phase I feasibility study was to identify the most appropriate evaluation methodologies, techniques, and tools to measure relevance, effectiveness, and impact of the CDRP Program in a consistent fashion. The feasibility study built upon the goals and objectives of the CDRP Program and explored mechanisms for conducting the comprehensive, multisite program-level evaluation. The feasibility study report provided tools—such as the CDRP Program Evaluation Logic Model and Evaluation Planning Matrix—that RRP/DCTD can use to implement the Phase II comprehensive evaluation of the CDRP Program.

The Phase II Evaluation Plan focuses on two sets of questions: process and outcome. The goals of the process questions are to ensure that each project is being implemented as planned and to identify intermediate factors that may have an influence on or may explain findings from the outcome questions. The intermediate process questions focus on each project's activities, challenges, outputs, and short-term results for the purpose of monitoring progress and making midcourse corrections or program adjustments when needed. Common intermediate process measures are related to early indicators of change (e.g., development of plans for procedure changes, requests for budgets to initiate new hires and/or implement new procedures)

[1] Throughout this evaluation plan, *Program* is used to refer to the overall multisite CDRP Program. Alternatively, *project* is used to refer to individual awardee grants.

that are precursors to longer-term changes. Thus, answers from intermediate process questions contribute to planning and conduct of the outcome component and inform outcome findings interpretation. Outcome questions systematically assess project accomplishments and activities that have led to attainment of CDRP intermediate and long-term goals. Relationships between project activities and their intended and unintended effects–based on findings from both the intermediate process questions and the final, overall outcome questions–will be identified to address why some project strategies worked better than others. The CDRP Program and Evaluation Conduct Timeline is shown as Exhibit 2 at the end of this document.

2.3 Use of Results

Results of this evaluation will be used to identify lessons learned that can be applied to a renewed and re-funded CDRP Program or other research and intervention programs related to reducing cancer health disparities and more effectively using telemedicine for improving patient care. For example, through the NCI's NAVCOM ([Patient] Navigation Committee), CDRP results from the Patient Navigator component will be shared with the Center to Reduce Cancer Health Disparities, which is conducting a more focused Patient Navigator Research Program to identify which types of Patient Navigation models are more effective; with the Center for Cancer Research Patient Navigator Academy, which is training Patient Navigators regarding how to find out about and refer patients to NIH Clinical Center cancer clinical trials; and with other NIH programs that may be involved in Patient Navigator activities. The NIH Clinical Center has an ongoing interest in community-based research findings related to reducing health disparities and assuring better representation of minorities in clinical research. By sharing evaluation findings related to identifying patient care barriers and possible facilitating factors experienced by CDRP study participants who are interested in participating in clinical research, along with findings about why minority and underserved populations do and do not voluntarily choose to participate in cancer clinical trials, this evaluation will enhance understanding of minority participation in clinical trials of all those involved in clinical trials research at the NIH. Sharing evaluation findings with the Center for Information Technology will facilitate disseminating CDRP Program findings to other programs, both nationally and internationally, using telemedicine to facilitate cancer research and improve treatment outcomes for all cancer patients. In addition, the findings of qualitative and quantitative evaluation of the four intervention methods—clinical trials, partnership/mentoring, TELESYNERGY®, and Patient Navigation—can be shared. Both Program successes and not-so-successful results will be disseminated through journal publications and presentations at professional meetings. For successful components, it may be possible to develop a technology transfer program to deliver intervention documentation and training to other communities. Evaluation findings from each component's questions, including process factors that had an impact on degree of success, will be shared with current CDRP projects so that improvements and corrective actions can be considered for implementation as existing projects continue beyond the end of the grant. If future funding is provided to continue the CDRP Program for another 5-year cycle, evaluation findings will be used to refine Program goals and objectives and improve progress and project outcomes.

CDRP Program stakeholders include radiation oncology staff within RRP/NCI, other Program Directors within the Division of Cancer Treatment and Diagnosis (DCTD), the NCI Executive Committee, other NCI and NIH programs, radiation oncologists in both academic and community settings, health administrators, and health disparities researchers. Results of this CDRP Program Evaluation will strengthen our understanding of the value of building clinical research capacity in community institutions that have not traditionally participated in clinical trials research. Also, these findings will inform NCI and NIH about approaches to supporting and encouraging collaborative partnerships both scientific research and cancer care delivery between academic research centers and communities experiencing excess cancer and other chronic disease burdens.

While the major impetus of the proposed Evaluation is to support responsible management of the CDRP Program, it is also important to NCI's commitment to the broader NIH community goal of reducing health disparities among populations experiencing excess disease burden. For example, one of the four components of the CDRP Program is to evaluate TELESYNERGY® within the projects by asking questions such as: (1) Did it facilitate patient care through improved patient access to care, clinical decision making and diagnosis? (2) Did it support research-related activities, patient consultation, and continuing education? and (3) Did users report increased proficiency and satisfaction with the system? Findings from such questions can be used by other treatment programs to support expanding this capability to other community and academic partnership disease projects and by the Center for Information Technology in its future telemedicine research and development.

Recruitment of minority, rural, and lower socioeconomic status populations into any type of clinical trial has always been problematic. Findings and results of the CDRP Program will provide indicators of recruitment techniques and methodologies that may apply to programs that address reduction of health disparities among populations affected with other chronic diseases.

Thus, CDRP Program Evaluation findings will have a trans-NIH aspect, as evidenced by Letters of Interest from several other ICs (provided in Appendix A) and as indicated above, the CDRP Program may through this evaluation inform and promote trans-NIH collaborations and future program developments in each of the four components, as well as in combination component programs.

2.4 Review of the Literature

During the feasibility study, a literature review was conducted to inform the development of the CDRP Program Evaluation Plan. This review examined published literature relevant to current knowledge about the characteristics of the CDRP program. This review included participation in clinical trials by minorities and underserved populations, conducting clinical research in minority populations through community-based institutions, partnerships between community-based and research institutions, the use of telemedicine, and the use of case-management similar to Patient Navigation. There is no evidence-based literature on the types of partnerships fostered by this Program or of the methodologies being used to reduce cancer health disparities through the combined intervention protocols being conducted. While individual methods for recruitment of underrepresented populations to cancer clinical trials have been evaluated, no evaluation exists that encompasses the four methodologies being tested by this Program. Thus, this CDRP Program of cancer research and intervention is unique.

2.5 Timelines of the Evaluation

Under current budget constraints, DCTD and NCI will need to make important decisions about future funding of intervention techniques being tested by the CDRP Program (e.g., expanding community-academic partnerships to support clinical trials and extending the use of TELESYNERGY®). There are numerous competing programmatic interests vying for limited resources, and decisions on whether to continue support for particular programs or program components (e.g., Patient Navigation) could be based on results of this evaluation. Although the CDRP Program will be continued through FY2008, support for future, similar efforts is uncertain without the results of a comprehensive outcome evaluation. As the Program approaches its last year, the Radiation Research Program will use the results of this proposed evaluation to decide whether to present and, if so, support a request to NCI for re-funding the program for another 5-year cycle.

The Program is now at about its midpoint; therefore, there is still sufficient time and opportunity, through the process question findings, to make midcourse corrections to enhance the Program's effectiveness and outcomes as well as ensure that all data are collected for a comprehensive evaluation that measures Program successes on multiple levels.

Findings from annual process questions will also allow DCTD to share information earlier then would be possible with just outcome evaluation questions at conclusion of the Program. This information may be useful to other NIH ICs confronting the challenge of whether to initiate similar programs or to determine how to evaluate program and component methodologies that are similar and in progress in other diseases.

SECTION 3: Evaluation Design

3.1 Key Questions to be Addressed (Evaluation Questions)

Because the CDRP Evaluation Plan will involve process and outcome questions, different types of evaluation questions will be asked. (See Appendix C: Evaluation Design Plan for the full list of evaluation questions.)

The five key evaluation questions to be addressed are:

1. Does the CDRP Program design contribute to our current knowledge of how to improve radiation oncology cancer treatment in populations experiencing health disparities and how to conduct clinical research in community-based health care institutions? *Evaluation Goals: 1, 2, 3, 6, 7, 10, 11*
2. Has there been an increase in radiation oncology clinical and translational research with populations experiencing cancer health disparities? Has clinical trial participation by target populations increased?
   Evaluation Goals: 1, 2, 3, 4, 6, 7, 8, 11
3. What is the influence of partnerships between awardee institutions and academic research centers on clinical research and patient outcomes at the awardee sites? *Evaluation Goals: 1, 2, 4, 5, 7, 8, 9,10*
4. What is the influence of TELESYNERGY® on building partnerships, facilitating clinical research, and improving treatment outcomes? *Evaluation Goals: 5, 10*
5. Has Patient Navigation facilitated access to cancer care and improvement of patient outcomes in the target populations? Has Patient Navigation improved/facilitated participation of minorities in clinical trials? *Evaluation Goals: 6, 11*

3.2 Target Populations for Data Collection

The primary groups about whom information is needed to answer study questions are: (1) cancer patients from targeted populations experiencing cancer health disparities; (2) Principal Investigators, participating radiation oncologists, and awardee institution staff; and (3) project Patient Navigators.

- Two cancer patient focus groups, each comprising about eight patients representing the target population and who have participated in the project, will be conducted at each grantee site. Approximately 96 patients of different genders and representing different types of radiation treatment received will discuss tailored issues at the end of Program years 3, 4, and 5.
- Data will be collected annually from the six grantee Principal Investigators, participating radiation oncologists (approximately six to eight), and senior staff from the multiple collaborating partners (approximately eight). This information will address their experience with their CDRP project and implementation processes and issues at their local site.
- Group interviews will be conducted annually with project Patient Navigators and Navigator-component support staff (about three to four project staff at each project site). The evaluation will collect information about their experience with the navigation process, overcoming patient clinical trial issues and patient care barriers at their local sites.

3.3 Key Variables

To conduct an effective CDRP Program Evaluation, develop and interpret findings, and prepare recommendations and lessons learned, the following key variables related to resources, population characteristics, project activities, project goals, and external community factors will be collected.

Program resource variables:

Amount of CDRP funding; duration of CDRP funding; cost of installation and maintenance of TELESYNERGY®; DCTD/RRP, PI, and awardee site staff FTEs; frequency and type (phone/e-mail; site visits) of contact by Program Director

Program population characteristic variables

Patients: race/ethnicity, gender, age, education, insurance, cancer site and stage, barriers to cancer treatment

PIs, co-PIs and radiation oncologists: institutional affiliation (awardee site); specialty/expertise; size and description of population served; number and cancer sites of patients treated in radiation oncology department

Partners/collaborators from partner institutions: institutional affiliation and position; specialty/expertise

Awardee institutions: catchment area and population characteristics (race/ethnicity, census count); institution bed size; number of patients treated in radiation oncology department

Program activity variables

PI meetings; site visits by Program Director; IRB approvals; TELESYNERGY® installation/training; Patient Navigator training; data collection training; grantee protocols (title, phase of trial, trial type, open and close dates for accrual)

Program Goals measurement variables

Process

Program Goal #1: ***Publications by grantees and partners in peer-reviewed journals and presentations at national conferences about the CDRP Program (Program Components 1 to 4).***

Performance Measures: Number of manuscripts submitted/published, presentations at national conferences/meetings

Comparison measures: Number of pre-CDRP publications and presentations at national conferences/meetings

Program Goal #2: ***Increased number of radiation oncology clinical trials offered at each awardee institution (Program Components 1 & 2)***

Performance Measures: Number, type, and accrual rate to radiation oncology clinical trials at each grantee site as a result of the CDRP Program; joint research endeavors with partners resulting from CDRP-supported research efforts; budget allocations for community facility research infrastructure and researcher support staff

Comparison measures: Prior to CDRP Program, number of radiation oncology clinical trials; number of joint research endeavors with academic institutions; budget allocations for community facility research infrastructure and researcher support staff

Program Goal #3: ***Increased numbers of patients from target populations participating in radiation oncology clinical trials (Program Components 1 & 4)***

Performance Measures: Number of eligible patients from target and general population consenting to, participating in, and completing radiation oncology clinical trials; clinical trial drop outs and reasons;

number of navigated patients participating in and completing clinical trials; reasons patients refuse to participate in clinical trials

Comparison Measures: Number of eligible patients refusing participation in clinical trials and reasons; number of patients from target and general population participating in cancer clinical trials prior to CDRP Program

Program Goal #4: ***Increased collaborative research and clinical consultation between grantees and academic research partners (Program Component 2)***

Performance Measures: Number (meetings, conference calls, e-mails) and type (protocol consultation, patient consultation, research plan development) of partnerships between academic research institutions and grantee sites; number of contacts between partners and grantees; number of new research activities related to partnerships

Comparison Measures: Number and type of partnerships between academic research institutions and grantee sites prior to CDRP Program implementation

Program Goal #5: ***Frequent use of TELESYNERGY® to facilitate collaboration and consultation between grantees & academic research partners (Program Components 2 & 3)***

Performance Measures: Frequency of use of TELESYNERGY® for patient consultation (diagnosis and clinical decision making), research development, continuing education

Comparison Measures: Prior to installation of TELESYNERGY® and training, methods and frequency of consulting with other researchers/providers about patient diagnosis and care, research, and continuing education

Program Goal #6: ***Patient Navigators who decrease barriers to receipt of cancer care services and participation in clinical trials experienced by targeted populations (Program Component 4)***

Performance Measures: Number of patients receiving Patient Navigation services; time from cancer diagnosis to initiation of treatment; time from initiation to completion of treatment; adherence to treatment protocol(s); case studies of patients who agreed to participate and who did not agree to participate, and identification of decision-making factors

Comparison Measures: Prior to CDRP Program implementation, time from cancer diagnosis to initiation of treatment; time from initiation to completion of treatment; adherence by patients to treatment protocol(s) being cared for by grantee radiation oncology departments

Outcome

Program Goal #7: ***Develop a sustainable community-based radiation oncology clinical research model by increasing knowledge of and skill in conducting clinical research with targeted populations in community-based institutions (Program Components 1 to 4)***

Performance Measures: Sustainability plan for each grantee site; case studies of community institution medical and administration personnel participation in plan development and positive actions taken to implement the plan; inclusion of multiyear budgets in plan, inclusion of multiyear staffing requirements in plan; discussion of feasibility of implementation, including barriers to and promoters of implementation

Comparison Measures: Previous research studies participation (start and completion dates)

Program Goal #8: ***Increased numbers of community-based clinical scientists engaged in radiation oncology clinical research (Program Components 1 & 2)***

Benchmarks: In order to measure increased participation of clinical scientists, the following benchmarks will be used based on benchmarks from the beginning of the program:

- The number of clinicians participating in cancer research at each community hospital grantee site will increase 25% (each year of years 3–5) from the application benchmark.
- The percent of clinical time (level of effort) devoted to clinical research by clinical scientists at each community grantee site will increase 10% (each year of years 3–5) from the application benchmark.
- Each grantee will submit one or more new grant application(s) related to one or more of the CDRP Program components annually (each year of years 3–5).
- Each community-based PI and/or Co-PI will make one or more presentations yearly about CDRP Program research and accomplishments at a regional, national, or international meeting (each year of years 2–5).

Performance Measures: Number of radiation oncologists and other providers at each grantee site involved in clinical research as a result of the CDRP Program; percent of clinical time (level of effort) devoted to clinical research; case studies of decision-making processes behind participation in clinical research, including pros and cons considered and decision making on level of effort to commit to conducting clinical research

Comparison Measure: Number of radiation oncologists and other providers and percent level of effort at each grantee site involved in clinical research prior to CDRP Program implementation

Program Goal #9: ***Establish sustainable partnerships for cancer treatment and research between academic institutions and community-based clinical researchers (Program Component 2)***

Operational Definition: Sustainable partnerships are ongoing joint research and clinical endeavors between partners (CDRP community hospital and academic medical center) that extend beyond the funding period of the grant. Each community-based hospital is required by the end of funding Year 4 to submit a sustainability plan with specific information on how they will maintain collaborative efforts with their academic partner(s) after conclusion of the grant. The following benchmark will be used:

> Each grantee will have a 5-year plan to sustain all grant activity components (clinical trials, partnerships, TELESYNERGY®, and Patient Navigation) after conclusion of the NCI grant.

Performance Measure: Number and type of joint research endeavors with partners resulting from CDRP-supported research efforts; case studies of impact of collaborations on community institution's radiation oncology department research activities, such as ability to hire community-based researchers and staff; sustainability plan in place

Comparison Measure: Number and type of joint research endeavors with academic research institutions and grantee sites prior to CDRP Program implementation

Program Goal #10: ***Effectively use the TELESYNERGY® telemedicine system to support clinical research and patient care (Program Component 3)***

Performance Measures: Case studies of types of patient and research consultations identified to be most significantly impacted by availability of TELESYNERGY® telemedicine systems

Comparison Measures: Methods and frequency of consulting with other researchers/providers about patient diagnosis and care, research, and continuing education prior to implementation of telemedicine system

Program Goal #11: ***Improve patient care and participation of targeted populations in clinical trials through support from Patient Navigators (Program Components 1 & 4)***

Performance Measures: Number of patients receiving Patient Navigation services; number of eligible patients consenting to clinical trials and number navigated; time from cancer diagnosis to initiation of treatment; time from initiation to completion of treatment; adherence to treatment protocol(s); case studies of patients who agreed to participate and who did not agree to participate with identification of participation decision-making factors; perceptions of value added by Patient Navigation

Comparison Measures: Time from cancer diagnosis to initiation of treatment; time from initiation to completion of treatment; adherence to treatment protocol(s) by patients being cared for by grantee radiation oncology departments prior to CDRP Program implementation

***External Factor Variables*.** The following will inform and provide context for interpretation of outcome data: problems encountered during the CDRP Program; reasons for the Program's success or lack thereof; types and frequency of interactions with collaborators during the CDRP Program performance period; PIs' and administrators' experiences implementing research in a community institution serving a disproportionate share of populations experiencing cancer health disparities; and unexpected positive and negative events (e.g., sale of grantee institution to a for-profit company, change in PI, hurricanes and other natural disasters) occurring during the period under examination.

3.4 Conceptual Framework

Exhibit 3 at the end of this document is a conceptual framework for the CDRP Program. The purpose of the Cooperative Agreement is to build research capacity and stabilize a clinical trial research program in radiation oncology in community-based institutions that care for a disproportionate share of racial/ethnic minority, low-income, and medically underserved populations. The target population for this evaluation consists of clinical researchers in community-based cancer facilities and targeted populations cared for by these organizations.

SECTION 4: Data Collection and Analysis

4.1 Data Sources (see Appendix C: Evaluation Design Plan)

The CDRP Program Evaluation will use two primary sources for collecting key variable data—archival data and new data. Prior to funding and initiation of the CDRP program, pre-measures were collected by grantees as part of their application. Post-measures will be collected in each of Years 3, 4, and 5.

4.1.1. Archival Data

The **CDRP Database,** established early in the Program, will provide data on all components of the Program. To ensure quality data going forward: (1) an instruction manual for data entry will be given to each site; (2) data entry personnel from each site will be identified; and (3) quarterly conference calls with the data entry personnel will identify problems with data quality and provide solutions. Data will be entered into the CDRP Database on a schedule mutually agreed upon with the CDRP Steering Committee.

Program-related written documents, including minutes from PI meetings, organizational charts, local cancer education and awareness programs, and media articles on Program components and/or

implementation will be reviewed. In addition, historical data on cancer incidence, prevalence, survival, and mortality and baseline data on clinical trials and research activities at the sites will be abstracted from the grantee applications and used to compare progress. These documents will provide information on project elements such as composition of the partnership; number, roles, and responsibilities of local project staff; and details on community activities. PIs or their proxies and the RRP/NCI Program Director will provide documents to the evaluator for review and record abstraction.

4.1.2. New Data

In-depth interviews with the PIs and partners will be conducted annually to gather information about their experience with the overall CDRP Program and its implementation at their local sites. In addition, questions related to their experience with each of the Program components—clinical trials, TELESYNERGY®, partnerships, and the Patient Navigator—will be asked. This will help identify successes and the processes that led to them, failures, lessons learned, and recommendations for future programs.

Patient focus groups will be conducted at the end of Program years 3, 4, and 5. The purpose of these focus groups is to identify patients' experiences with: (1) clinical trials; (2) cancer care and treatment; (3) TELESYNERY®; and (4) Patient Navigator services. The Program Evaluator will develop a moderator's guide.

Group interviews with Patient Navigators and Navigator support staff will be conducted annually to gather information about their experience with Navigation at their local sites. This will help identify what worked and the processes that led to these successes, failures, lessons learned, and recommendations for future programs.

Surveys on issues related to recruitment to clinical trials will be administered to PIs, Program Coordinators, and Patient Navigators to gather data on facilitators of and barriers to recruitment of targeted populations to clinical trials.

4.2 Data Collection Strategies

The Evaluation will use a mixed-method design that combines quantitative and qualitative techniques to develop a full picture of the reasons the Program is producing documented outcomes. The same data collection strategies will be employed for each of the evaluation questions to obtain new data and retrieve archival data for analysis.

4.2.1. New Data Collection

New data will be collected annually and at the end of the funding period from all CDRP PIs, associated radiation oncologists, and partners via in-depth guided interviews. Information from all Patient Navigators and Navigator support staff will be collected annually through group interviews.

Two patient focus groups, each comprising approximately eight patients of both genders and with different types of cancer that represent the target population will be conducted at each grantee site at the end of Program years 3, 4, and 5. Each focus group will last up to 1.5 hours. The Program Evaluator will develop a moderator's guide of general discussion issues. The Evaluation contractor will work with each grantee site to solicit representative patients for participation.

In-person surveys on issues related to recruitment to clinical trials will be administered to all PIs, Project Coordinators, and Patient Navigators to gather data on facilitators of and barriers to recruitment of targeted populations to clinical trials.

Yearly interviews and focus group for the process evaluation are needed because of the staggered program implementation. The CDRP Program provides funding for 5 years; however, two awards were made in 2002

with four additional awards made in 2003. Therefore, the grants made to the first awardees will end in one and one-half years. This will necessitate collecting formative evaluation data as soon as possible.

The evaluation contractor provides independent evaluators who will conduct annual interviews with the PIs and navigators, and focus groups with patients. These interviews and focus groups will give each program site an opportunity to respond to the five key evaluation questions (Section 3.1 of the Evaluation Set-Aside Application) including changes over the previous year.

4.2.2. Archival Data Collection

Archival data will be collected by extracting information from the CDRP Database and Program-related documents. Comparison with previous history and baseline data obtained before Program initiation can be used to measure change. Expert judgment may be employed to determine the amount of change needed to find the evidence of impact convincing.

4.3. Comparison Group

To strengthen the design and subsequent findings, six similar community-based radiation oncology facilities will be surveyed using the same evaluation metrics about their independent and collaborative clinical research capabilities and current participation in clinical trials. These comparison sites will be chosen based on the same criteria as stated in the RFA and used as one factor to evaluate awarded CDRP grantees. The criteria include:

- The comparison programs must be from health care institutions accredited by the Joint Commission on Accreditation of Health Organizations or free-standing cancer centers accredited by a nationally recognized accrediting body such as the American College of Radiology, either in the United States or in territories under U.S. jurisdiction.
- The comparison programs must be the primary provider of radiation oncology care to one or more populations identified with cancer-related health disparities (e.g., African Americans, Asians, Hispanics, Latinos, Native Americans, Alaskan Natives, Native Hawaiians, Pacific Islanders and/or those with low socioeconomic status as defined by the Federal poverty level or the state-defined level, if lower) at a percentage greater than the state average of that population according to the 2000 U.S. Census Bureau statistics, and have a greater cancer incidence and/or mortality than the national average according to NCI data.

4.4 New Data Collection Instruments

In order to collect prescribed new data discussed above, a number of focus group general-issue guides and interview forms will be developed or collected from published literature. In addition, data elements will be added to the existing CDRP Database, as described below.

4.4.1. Survey on Issues Related to Recruitment of Targeted Populations to Clinical Trials With Program Coordinators and Patient Navigators

Information on facilitators of and barriers to recruitment of targeted populations to cancer clinical trials will be obtained annually from the grantee PIs, Program Coordinators, and Patient Navigators at the six project sites. Areas to be examined include recruitment strategies, recruitment goals, and barriers to and promoters of participation in clinical trials (e.g., access, knowledge, attitudes, eligibility, fatalism, religiosity/spirituality, altruism, stage of disease, and availability of no-cost treatment). Other questions will deal with variations in participation by variables such as gender and age. Health care providers' attitudes and perceptions about recruitment of and strategies to enroll targeted populations will be explored. Each of these surveys will be tailored to the specific activities and patient interfaces of the Program Coordinators and Patient Navigators. Therefore, no specific survey form will be used with more than nine individuals.

The recent AHRQ report[2] on recruitment of underrepresented populations will be used to guide the development of these survey forms. The surveys will be administered in face-to-face interviews conducted by senior evaluation researchers or research associates. There will be about 25 items on each survey form to address the issues described above. Most questions will elicit open-ended responses and, with permission of interviewees, will be tape-recorded and transcribed.

4.4.2. Additions to CDRP Database

As described above in *Section 4.1.1*, a CDRP Web-based database already exists that collects information to be used in the Program Evaluation. Data elements currently being collected will be expanded in the CDRP Database, such as resource costs (e.g., number of full-time employees, new capital equipment, videoconferencing maintenance, and training costs), patient socioeconomic status (using the Census Bureau Poverty Index), and publications. Additional data elements may be added to the Database based on results and findings from the initial annual process questions to ensure a comprehensive outcome evaluation at the conclusion of the Program.

4.5 Clearance Requirements

Required qualitative and quantitative data will be collected through in-depth guided discussions and focus groups of various types of individuals. Each discussion/focus group will be tailored to the specific individual or group characteristics such that the same questions are not asked of more than nine individuals. Thus, these data collection activities will not require OMB clearance. New surveys for Program Coordinators and Patient Navigators, as described above, will not be used with more than nine individuals, so again, OMB regulations do not require clearance to collect these data.

The general discussion guide for patient focus groups will be developed in collaboration with the CDRP Program Director, members of the Advisory Committee, and grantee-site investigators. Once developed, the general discussion guide, along with a focus group recruitment and conduct procedures manual and a data collection Informed Consent Form will be given to each grantee Principal Investigator for submission to and approval by his or her respective Institutional Review Board (IRB). Patient focus groups will be conducted only after the respective site IRB has approved the discussion guide, Informed Consent, and patient recruitment and interviewing procedures. Revisions will be made to the guide, form, and procedures as required by local IRBs. Any subsequent revisions required based upon actual field use during the initial process component will again be submitted to each local IRB for review and approval.

4.6 Data Integrity

Senior evaluation researchers or a research associate will conduct all interviews and guided discussions. The research associates will receive training in conducting telephone and face-to-face surveys. All interviews will be conducted using computer-assisted personal interview software to minimize data entry errors. All focus groups will be facilitated by one of the senior evaluation researchers, who are experienced in conducting focus groups. A research associate will capture important concepts and issues that arise during these meetings. The focus groups will also be tape-recorded and transcribed to further ensure the informational integrity of captured concepts and issues. Archival data will serve as a reliability check for information reported during interviews.

Data for the process and outcome measures, such as publications and presentations pertinent to the topics supported by the CDRP Program, will be provided directly by the researchers themselves, as they are the best and most reliable sources of information concerning whether outputs they have generated are a result of

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[2] Ford J, Howerton M, Bolen S, Gary T, Lai G, Tilburt J, et al. Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials. Evidence Report/Technology Assessment No. 122 (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 290-02-0018.). Rockville, MD: Agency for Healthcare Research and Quality; 2005.

their CDRP participation. However, information provided by the Investigators will be crosschecked by independent database searches (e.g., publication search through PubMed and other relevant databases and grant search through NIH IMPAC II). Database searches to identify publications by CDRP-funded researchers will be conducted by a research librarian with extensive experience in this task.

Data quality control and quality assurance procedures will be developed and implemented by the senior evaluation researchers and applied to all collected data. This will include procedures to ensure accuracy and consistency in data entry, data manipulation, and calculation.

4.7 Ethical Considerations

Minimizing respondent burden is one of the primary considerations in designing focus group guides and survey instruments. We estimate that individual interviews will not exceed 30 minutes in duration and focus groups will not exceed 1.5 hours in length. Experienced focus group facilitators (i.e., senior evaluation researchers) will conduct the focus groups and are experienced at determining when a focus group has communicated all relevant information required on specific topics.

To safeguard confidentiality and security of information contained in the CDRP Database, the non-Government contractor, upon signing of a confidentiality agreement, will be provided temporary usernames and passwords for database access. Computerized files will be stored in a secure network location, and all paper copies of documents reviewed will be kept in a locked file drawer and shredded upon completion of the final report. Identifying information will not be linked in any way to interviewee responses, and data analysis and reporting will not include any personal or otherwise identifying information.

4.8 Data Preparation

Quantitative data obtained from interviews, record reviews, and other modalities of data collection will be entered into an appropriate relational database and analyzed using SAS for quantitative response data. Data from in-depth guided interviews and focus groups will first be transcribed into Microsoft Word documents and then analyzed for issues and patterns using ATLAS.ti. The senior evaluation researchers will prepare coding manuals. Inter-rater reliability checks for coding consistency will also be conducted. Patterns and issues identified from the focus groups through the coding process will be crosschecked against patterns and issues identified in the research associates' focus group notes.

4.9 Data Analysis

Each program component—clinical trials, partnership, TELESYNERGY®, and Patient Navigator—will be analyzed to isolate important findings; then, sources of information will be combined to analyze the overall Program and linkages between/among components.

4.9.1. Quantitative Methods

The CDRP Database will be mined to provide descriptive statistics (e.g., frequencies, means, cross-tabs) to answer evaluation questions for the overall CDRP Program and for individual components. These data will be examined quarterly to monitor progress and detect any problems that require project intervention. More complex analyses and causal modeling, such as regression analysis, may be possible depending on the quality and quantity of data. The ability to conduct complex analyses will initially be assessed during the process component of the evaluation and again during the outcome component. If data are adequate to support complex analyses, it is anticipated that these will be performed as part of the outcome component.

Historical data on cancer incidence, prevalence, survival, and mortality and baseline data on clinical trials and research activities at the sites will be compared with end-of-program data. Descriptive data from other sources, such as Program-related written documents, will be used to complement understanding and measurement of Program impact. Resource cost-allocation analyses will provide descriptive information about the ratio of costs to interventions (e.g., one Patient Navigator FTE per number of patient encounters).

4.9.2. Qualitative Methods

Qualitative measures include patient focus groups and in-depth, open-ended interviews with PIs, Program Coordinators, partnership senior staff, and Patient Navigators. Data will be transcribed verbatim. Coding (i.e., categorizing) of the data and thematic analysis of the text will be conducted by a minimum of two evaluators. Intended and unintended successes, failures, critical incidents, lessons learned, and recommendations for future programs will be identified. ATLAS.ti qualitative analysis software will be used for this process.

4.10 Limitations

Limitations and techniques to address the indicated issues stated above follow.

4.10.1. Self-Reported Data

The Data Quality Review Subcommittee, a subcommittee of the Evaluation Advisory Committee, (see Section 6.2) will review all self-report data to identify any patterns of bias or inconsistencies. In addition, quantitative, objective information, such as accruals to clinical trials and TELESYNERGY™ usage statistics for diagnosis and treatment monitoring will be used to assess the accuracy of self-report responses.

4.10.2. Intrusive Methods and Low Response Rates

The administrative and funding instrument used for this program is a cooperative agreement (U56). Under this agreement, the CDRP Steering Committee (comprised of the principal investigators from each grantee site and the NCI Project Officer) agreed as a component of grant award, to provide information such as frequency and type of contacts (e.g., emails, conference calls, video conferences) between grantees and academic partners to evaluate utility of the partnerships, TELESYNERGY™ use data, and other similar measures of project achievements and accomplishments. Under this mechanism, the NCI Project Officer has increased authority and responsibility to ensure this information is provided on a timely basis for program progress monitoring and evaluation.

4.10.3. Generalizability of Findings

Although only statements about grantee programs will be possible, lessons learned from this study can be used to promote, plan, and implement and/or improve or extend clinical research among underserved populations in other settings.

4.10.4. Justification for Evaluation of Outcome Goals

Each of the five Outcome Goals described on page 2 of this Evaluation Set-Aside Application (Items 7-11) can be reasonably evaluated for each project and for the overall CDRP. By the time the first evaluation is conducted, two of the projects will have been in operation for 4 years (2002-2006) and four will have been in operation for 3 years (2003-2006). For the two initial programs, they are required by the terms of the Cooperative Agreement grant to have their sustainability plan (Outcome Goal 1) in place for review and approval, and the other four projects will be in the process of plan preparation, so that an outline will be available for review.

As indicated above, metrics have been defined and starting benchmarks are already collected and available to begin evaluation of progress towards and likely achievement of the other, more quantifiable outcome goals for the CDRP. Thus, NCI believes that the projects have been in existence long enough to justify an evaluation of progress towards outcome goals at this time.

SECTION 5: Evaluation Results

5.1 Products of the Evaluation

This evaluation will consist of two annual sets of process questions and accompanying progress findings reports–one for each annual process review conducted–and a final evaluation report based on the outcome questions and reflecting findings and conclusions after the end of the grant period. The primary purpose of the two annual progress reports is to notify NCI Program Officials and other stakeholders about how the Program is being implemented, accomplishments and progress to date, and recommended midcourse changes that may be needed to meet Program and/or grant project objectives. The final evaluation report will provide evidence about the Program's attainment of goals and expected outcomes. In addition, conclusions will be strengthened by: (1) summarizing plausible mechanisms of change (e.g., Patient Navigator Program led to decreased patient dropout from clinical trials); (2) delineating temporal sequences between activities (e.g., established partnership) and effects (e.g., increased research capacity); and (3) showing that the effects can be repeated. Publication of evaluation findings in peer-reviewed journals is anticipated so that they can be shared in the larger research and cancer care communities.

5.2 Timing and Use of Evaluation Reports

In order for the results of this evaluation to be useful for making future decisions at NCI, timing of evaluation activities will be coordinated with NCI's decision-making schedule. To accomplish this each Annual Evaluation Report, expected to be available by the end of December of each year, will be used (1) to make changes in and recommendations to the projects and/or the overall CDRP and, (2) to inform NCI senior leadership on the ongoing status of the CDRP program. This information will also be used within the next 18 months to begin seeking continued funding of this program beyond the initial 5-year period, if warranted by evaluation results. Since the first of these projects will be concluding in 2007, it is critical that (1) information be collected and evaluated immediately on interim successes, accomplishments, problem areas, and progress issues in order for the NCI's Radiation Research Program to decide whether to seek continuation funding, and if warranted, to do so. This initial individual grantee project evaluation information, to be available by the end of December 2006 will also be used by NCI to determine what changes or additions in program requirements and activities should be incorporated into a new cycle of funding to further the overall objectives of the CDRP.

Information from the summative (outcomes) evaluations, to be available by December 2007 for the first two sites and by December 2008 for the additional four sites will add to our knowledge concerning best practices and lessons learned for establishing, stabilizing, and conducting clinical trials in community-based institutions with large populations experiencing cancer health disparities. Best practices and lessons learned about specific components of this program such as telemedicine and accrual of minority populations to clinical trials are of special interest to both intramural programs at NIH such as the Center for Information Technology and the NIH Clinical Center as well as extramural programs. (Exhibit 2, page 20 shows the various reports timeline.)

5.3 Dissemination of Results

Each of these products of the evaluation will be disseminated by making electronic versions available on the NIH Office of Evaluation Web site, as well as on the NCI DCTD/RRP Web site. Products will be shared with interested staff from multiple ICs. Specifically, meetings and presentations will be scheduled with the NIH Clinical Center, Center for Information Technology, and the National Center on Minority Health and Health Disparities to discuss Program findings applicable to those organizations (e.g., findings regarding recruitment of minorities into clinical trials, findings on effective use of telemedicine, findings on how various CRDP Program components show positive trends in reducing cancer health disparities). Findings from this study will also be shared at research meetings and conferences, such as NCI-funded Radiation Therapy Oncology Group (RTOG) meetings, Center for Cancer Research meetings, NCI Health Disparities

meetings, Center to Reduce Cancer Health Disparities meetings, and similar NCI and trans-NIH meetings, as well as professional association meetings (e.g., ASTRO, ASCO, APHA).

SECTION 6: Project Management

6.1 Project Implementation

An independent contractor will conduct the Evaluation. The contractor selected to conduct the feasibility study will be asked to implement the full Evaluation. The contractor has: (1) become familiar with all the grantee projects through a thorough review of their applications and annual progress reports; (2) become known to the grantee PIs through attendance at semiannual meetings; (3) become proficient in navigating the CDRP management database systems to retrieve information quickly; (4) developed an effective working relationship and rapport with the Project Officer; and (5) demonstrated its reliability in accomplishing evaluation efforts at a high level of quality according to the time involved. This contractor was initially selected based on its expertise in designing and conducting survey research and evaluations as well as its knowledge of research methodology and statistics. This contractor is also a woman-owned enterprise. Working with the same contractor with such a high level of prior knowledge and CDRP Program expertise is very important to the success of this evaluation. Continuing the Program Evaluation with the same contractor who performed the feasibility study would result in a much more efficient use of the funds being requested as opposed to issuing a new Request for Proposals and selecting a new contractor less familiar with the CDRP Program.

6.2 Advisory Committee

The advisory committee, which will guide this evaluation study, will consist of the following members:

- Frank Govern, Ph.D., Program Director, NCI, Oncology Outreach (Chairman)
- Larry Solomon, Ph.D., Senior Evaluation Scientist, NCI,
  Office of Science Planning and Assessment
- Norman Coleman, M.D. Associate Director, NCI DCTD Radiation Research Program
- Ted Trimble, M.D., NCI DCTD Clinical Trials Evaluation Program
- Martin Ojong-Ntui, M.D., Chief, Radiation Oncology,
  George Washington University Cancer Center
- Paul Johnson, Ph.D., Program Analyst, NICHD, Office of Science Policy Analysis & Communication

The **six** committee members will provide advice on programmatic needs and the types of information RRP hopes to gain from the Evaluation. The members have been selected for their expertise and extensive experience in radiation oncology, clinical trials research, community-based research, and program evaluation. They will provide guidance to ensure the validity of the evaluation design, approach, and data analysis.

The Advisory Committee will meet the first year semi-annually, and thereafter annually. Doing the first year initial meeting, the Committee will receive a project and evaluation plan briefing and be asked to comment on any changes or additions needed for the planned evaluation. The second first-year Advisory Committee Meeting and subsequent annual meetings will provide updates on changes and evaluation results to date. The Committee will be asked to make recommendations for changes and evaluation needs for each subsequent evaluation year, based on presented evaluation findings and conclusions. Annual evaluation reports will be sent to the Advisory Committee prior to each meeting for review, comment, discussion, and recommendations at the meeting.

A Data Quality Review Subcommittee will be established from members of the Advisory Committee to review data quality and make recommendations for improvements and/or additions. The Data Quality Review Subcommittee will be composed of 3 members:

- 2 evaluation experts not in the field of radiation oncology or cancer clinical trials, who are government employees—Paul Johnson, PhD and Larry Solomon, PhD.
- 1 expert in radiology-oncology research who is not an evaluation expert and is not associated with the NCI—Martin Ojong-Ntui, MD.

The Data Quality Subcommittee will meet annually, approximately 3 months prior to the scheduled Advisory Committee Meeting, to review qualitative and quantitative data collection methods and data analyses for accuracy, biases, interpretations and conclusions from the evaluation report. They will make comments and recommendations to the NCI Project Officer to maintain and/or improve data management and data quality assurance. The Subcommittee's report to the NCI Project Officer will be shared with the Advisory Committee.

6.3 Role of the Project Officer

The project officer will oversee conduct of the evaluation and ensure its success by (1) requiring the Cooperative Agreement grantee sites to provide access to necessary data for the evaluation; (2) ensuring that the evaluation contractor accurately collects, analyses, and reports evaluation results; (3) providing input for the evaluation for subsequent years; and (4) presenting annual interim progress and summative evaluation results (annual reports) to NCI senior management.

6.4 Minimizing Potential Conflict of Interest of Project Staff

Three members of the Advisory Committee—Larry Solomon PhD, Paul Johnson PhD, and Martin Ojong-Ntui, MD—have no vested interest in the outcomes of the program evaluation. An additional member—Ted Trimble M.D. is in the same division where the CDRP Program is based; however, he has no direct involvement in this program.

The evaluator contractor is an independent group of experts with no vested interest in the outcome of the program evaluation other than accurate reports. Therefore, there is minimal conflict of interest.

6.5 Estimated Timeline for the Evaluation

Based on the length of time and staff hours estimated for conducting the process and outcome components during conduct of the feasibility study, we estimate that it will take approximately 12 months to complete each component (process and outcome questions) of the full Evaluation.

Task 1:	Planning Meetings to Update/Refine Evaluation Plan and Implementation Procedures	Months 1–2
Task 2	Sample Selection Procedures and New Survey Forms Development and Documentation	Months 2–3
Task 3	Modification of Data Collected in CDRP Database and Preparation of Users Manuals for Field Sites	Months 3–5
Task 4	Documentation for IRB Approval of Patient Interviews and Submission to PIs for Local IRB Approvals	Months 5–6
Task 5	Conduct of Site Visit Interviews and Focus Groups	Months 6–9
Task 6	Analysis of Qualitative and Quantitative Data	Months 8–11
Task 7	Preparation of Interim Progress/Final Reports	Months 11–12

SECTION 7: Budget Estimate

7.1 Estimated Cost

The time required for Evaluation Plan implementation, data collection, data analysis, and reporting of progress, outcomes, and lessons learned was estimated during the feasibility study; it has been determined that approximately 1,550 hours of effort per year will be required for the tasks described above, with a 4-year total of 6,194 hours. Funds in the amount of $499,999 will be needed to cover the expenses associated with the 4-year evaluation effort.

7.2 Anticipated Funding Sources

		Estimated Amount From Each Funding Source		
Fiscal Year	Estimated Cost	Evaluation Set-Aside Funds	IC Funds	Other Funds
2006	$139,815	$139,815		
2007	$133,391	$133,391		
2008	$121,952	$121,952		
2009	$104,841	$104,841		
TOTAL	$499,999	$499,999		

Exhibit 1: TELESYNERGY®: Linking the U.S. and World through the Application of a Robust, Multi-image Telemedicine System in the Support of Cancer Research

Researchers at the National Cancer Institute have collaborated with the National Institutes of Health's Center for Information Technology (CIT) to develop TELESYNERGY®, a state-of-the-art telemedicine system with broadcast-quality teleconferencing capabilities that is capable of transmitting many medical images including diagnostic-quality radiology and pathology images. TELESYNERGY® allows numerous collaborators at greatly separated geographic sites to interact as if they were in the same room, viewing and discussing the same medical images in real time.

The original version of the TELESYNERGY® system is equipped with software – largely custom-developed by staff of the Telemedicine and Applied Imaging Section at the NIH Centre for Information Technology – to allow simultaneous display of high-resolution medical images. The original version of TELESYNERGY® includes microscopes and video cameras that can be operated remotely, allowing participants to manipulate biopsy samples from any participating site, with the results of that manipulation being instantly transmitted to other participants. A patient exam camera allows high-resolution view of dermatological lesions, skin coloration, and other physical signs during a patient examination. CIT continues to develop the TELESYNERGY® system in accordance with the needs of other NIH Institutes and the Clinical Center, in support of their intramural and extramural programs. The NCI continues to deploy the TELESYNERGY® system to enhance cancer treatment and research.

Because it can eliminate geographical barriers, telemedicine has the power to reduce cancer and other health disparities by bringing high quality care to underserved populations. NCI is already utilizing telemedicine is its goal of eliminating cancer health disparities, by making the TELESYNERGY® system a key component in its Cancer Disparities Research Partnership program. This program supports radiation oncology clinical trials in institutions that care for disproportionate number of medically underserved, low-income, ethnic, and minority populations. The program pairs these institutions with experienced institutions actively involved in NCI-sponsored research, and relies on TELESYNERGY® to facilitate communication and consultation between partner institutions. By making the knowledge and experience of oncology experts accessible regardless of where in the world those experts are, TELESYNERGY® is enabling the dramatic acceleration of cancer research and improved cancer care by facilitating unique collaborations and connections.

Figure: NCI's TELESYNERGY® Suite located at Executive Plaza North, Bethesda, MD

Exhibit 2: CDRP Program and Evaluation Contract Conduct

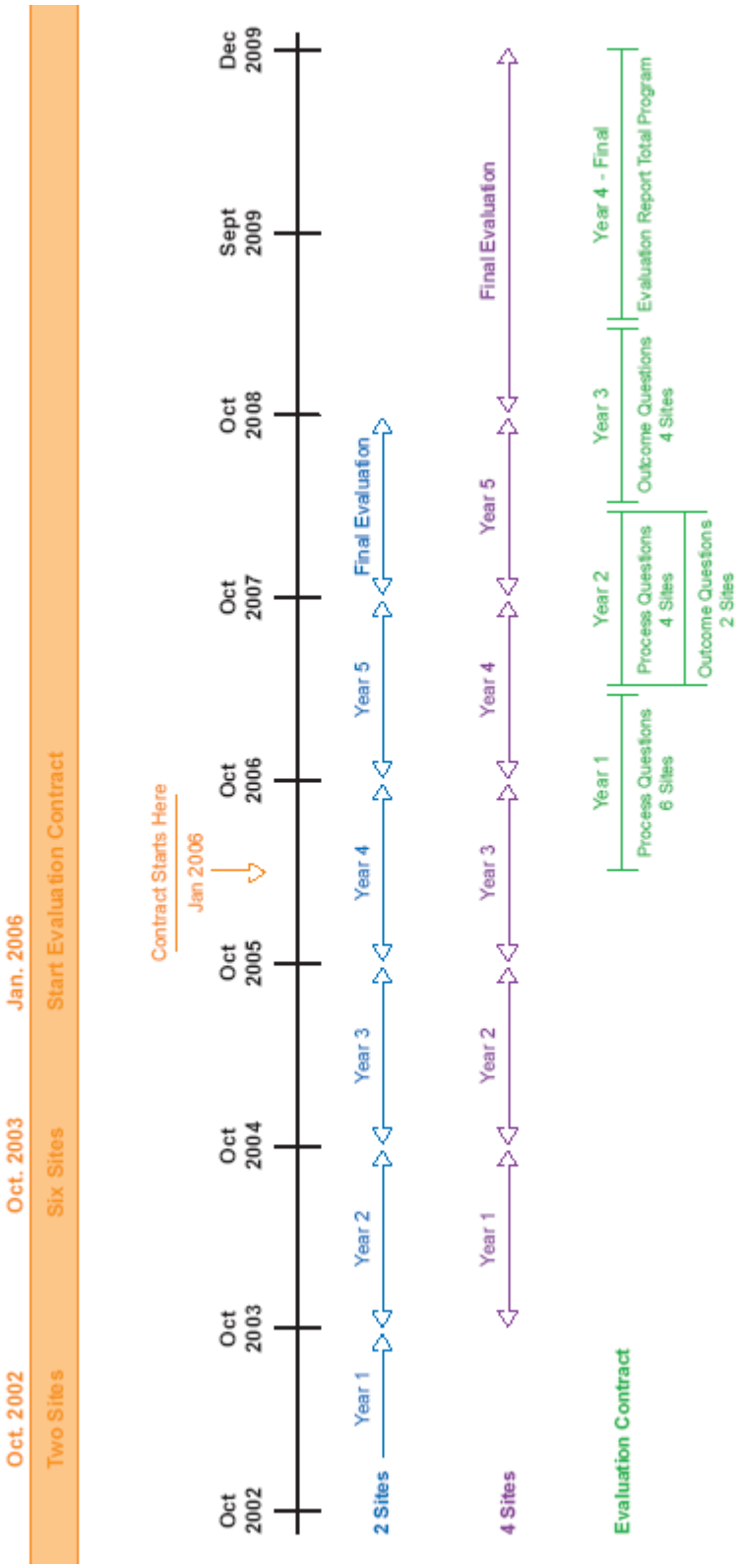
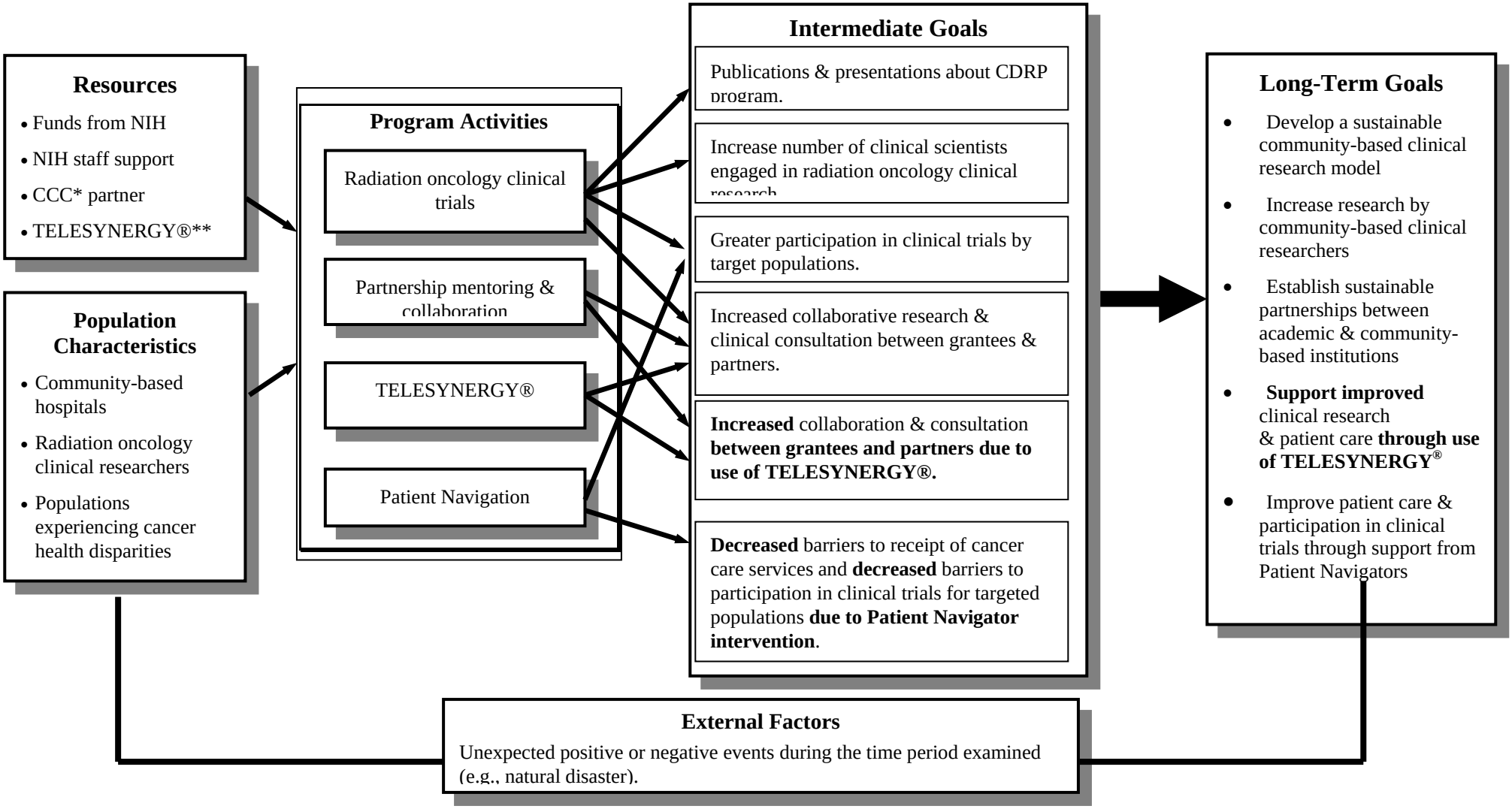


Exhibit 3: CDRP Program Conceptual Framework

The purpose of this cooperative agreement is to build research capacity and stabilize a clinical trials research program in radiation oncology in community-based institutions that care for a disproportionate share of racial/ethnic minorities, low-income and medically underserved populations. The target population for this evaluation consists of clinical researchers in community-based cancer institutions and targeted populations cared for by these institutions



* Comprehensive Cancer Center (CCC) partners are academic research institutions actively involved in NCI-sponsored cancer research.

** TELESYNERGY®, a telemedicine system installed at each CDRP grantee institution and its primary partner, augments the partnerships.

APPENDICES

APPENDIX A

Letters of Interest from NIH ICs

December 8, 2005

Linda Kupfer, PhD
Acting Director
Office of Evaluation
Office of Science Policy
Office of the Director, National Institutes of Health

Dear Dr. Kupfer,

I am writing to express my strong support for the Program Evaluation Set-Aside Funding Application being submitted by Dr. Frank Govern to conduct a formal and thorough objective evaluation of the National Cancer Institute's Cancer Disparities Research Partnership Program (CDRP). The Clinical Center has an active interest in a broad range of topics related to health disparities and assuring better representation of minorities in clinical research. My particular focus is in enhancing understanding of clinical nurses of both the barriers and possible facilitating factors experienced by people from diverse backgrounds who are potentially interested in participating in clinical research. Our research activities include studies in the local community as well as studies of patient perceptions of barriers to access and equal treatment. We have been interested supporters of the NCI Cancer Disparities Research Partnership Program, and would be interested in findings from a program evaluation.

I believe other NIH institutes, centers and extramural communities, many of whom have been colleagues in our research efforts, would be interested in the results and "lessons learned" through this evaluation including 1) whether the CDRP Program's non-traditional design contributes to our current knowledge of how to increase the participation on clinical trials of populations experiencing cancer health disparities; 2) has the program identified more effective methods to better conduct clinical research in community-based hospitals serving minority populations and 3) most importantly, has patient outcomes improved through CDRP program efforts.

On behalf of the Clinical Center, I enthusiastically endorse Dr. Govern's application for evaluation set-aside funding for the CDRP Program. Dr. Govern's efforts to obtain objective answers to the above questions, and other planned areas of evaluation, will be greatly beneficial to developing more effective strategies to best address and reduce health disparities experienced by our citizens.

Very truly yours,

Clare Hastings

Clare Hastings, RN, PhD, FAAN
Chief, Nursing and Patient Care Services,
Clinical Center, National Institutes of Health

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E-mail: Robert.Martino@nih.gov

October 25, 2005

Subject: Letter of Support for the Cancer Disparities Research Partnership Program Evaluation

To Whom It May Concern,

I would like to express my enthusiastic support for the Cancer Disparities Research Partnership (CDRP) Program Evaluation that is being proposed by Dr. Frank Govern of the National Cancer Institute (NCI). Dr. Govern's plan to seek answers to a number of important questions over the next three years regarding the use of telemedicine within the CDRP program will greatly benefit our work at the Center for Information Technology (CIT) and be useful to many clinical and scientific research centers throughout the world.

Members of my organization at CIT and I have collaborated with Dr. Govern over the last seven years for a number of NCI initiatives. One example is the international program known as the Ireland - Northern Ireland – NCI Cancer Consortium. An important part of these initiatives, consisting of geographically distributed partners, was the development of useful telemedicine systems at participating sites. Dr. Govern's contributions to these efforts have been essential to the establishment of the telemedicine system known as TELESYNERGY®. The system has been used for face-to-face consultation among multiple participant sites, while transmitting simultaneous high-resolution images to all sites. His leadership in using TELESYNERGY® to improve cancer treatment continues with the CDRP Program.

Dr. Govern will look for the answers to questions such as how has TELESYNERGY® facilitated patient care through better patient access, improved decision making and more accurate diagnosis? He will also investigate how TELESYNERGY® has enhanced research and education activities. We have implemented telemedicine systems throughout the United States and are participating in a number of international telemedicine efforts for the NIH. I know that the outcome of his research will be of interest to the medical and technical staff at these many locations.

I am confident that Dr. Govern's work will lead to advances in the use of telemedicine. I look forward to continuing my collaboration with him and benefiting from the results of his research.

Sincerely,

Robert L. Martino

Robert L. Martino, Ph.D.
Director, Division of Computational Bioscience
Center for Information Technology

APPENDIX B: References

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APPENDIX C: Evaluation Design Plan

PROJECT TITLE: Cancer Disparities Research Partnership (CDRP) Program Intermediate Process and Outcome Evaluations

DATE: November 28, 2005

	Key Questions (s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Limitations	What the Analysis Will Allow You to Say
Evaluation Question #1: Does CDRP Program design contribute to current knowledge of how to improve radiation oncology cancer treatment in populations experiencing health disparities and how to conduct clinical research in community-based health care institutions?							
1)	Did funding result in publication and presentation of papers the first 5 years?	Physical documentation	Progress reports; PubMed; other professional journal database resources; grantee institution; PIs	Data extraction and document retrieval, structured questionnaires	Descriptive statistics	May miss submitted but not accepted papers.	Precise statements about conducting radiation oncology clinical research in community-based institutions.
2)	What has the experience of grantee officials and partners been regarding the nontraditional model of funding used by the CDRP Program in facilitating the accomplishment of Program goals?	Physical documentation; funding levels; cost information	Progress reports; program documents; grantee institution; PIs and partners	Data extraction and document retrieval, structured interviews	Descriptive statistics, qualitative analysis, cost-allocation analysis	Data quality and reliability, access to records	Precise statements about the sample; possible extrapolation to larger universe; cost of various program options
3)	Is the 4-component model used by the CDRP Program likely to facilitate the accomplishment of Program goals?	Physical documentation; clinical trials participant rates	Progress reports; grantee and partner institution PIs, Co-PIs, and staff	Data extraction and document retrieval, structured interviews, structured questionnaires	Descriptive statistics, qualitative analysis	Data quality and reliability	Precise statements about the sample; possible extrapolation to larger universe; impact of program changes

	Key Questions (s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Limitations	What the Analysis Will Allow You to Say
4)	What are the grantee institutions' plans for sustaining the CDRP Program?	Physical documentation	Program documents (Steering Committee minutes); program sustainability plan	Document retrieval	Qualitative analysis	Data quality and reliability	Precise statements about the sample
5)	What is the nature of the radiation oncology clinical research conducted by grantees (e.g., independent or collaborative; by cancer type & phase; by interventions—treatment & palliative)? What lessons have awardees learned in implementing clinical trial studies (e.g., IRB approval, awardee institution issues, RTOG applications)?	Documentary evidence; clinical trial participation rates; Program criteria	Program documents; databases; PIs, Co-PIs, partners	Data extraction; structured interviews and questionnaires; document retrieval	Descriptive statistics, qualitative analysis	Data quality and reliability, access to records	Precise statements about sample; possible extrapolation to larger universe
Evaluation Question #2: Has there been an increase in radiation oncology clinical and translational research with populations experiencing cancer health disparities? Has clinical trial participation by target populations increased?							
6)	Did the CDRP Program result in increased clinical and translational research with populations experiencing cancer health disparities (i.e., targeted populations)? Are certain target populations more likely to participate in clinical trials, & why?	Participation rates; programmatic criteria	Program documentation; databases; stakeholders	Data extraction; semistructured interviews and questionnaires.	Descriptive statistics, qualitative analysis	Data quality and reliability	Precise statements about sample; anecdotal information
7)	Have community-based clinical researchers improved their knowledge, attitudes, & practice of radiation oncology research?	Testimonial evidence	PIs, Co-PIs, and other participating clinicians	Semistructured interviews	Qualitative analysis	Data quality and reliability	Precise statements about sample, anecdotal information

	Key Questions (s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Limitations	What the Analysis Will Allow You to Say
Evaluation Question #3: What is the influence of partnerships between awardee institutions and academic research centers on clinical research and patient outcomes at awardee sites?							
8)	What is the nature of collaboration between grantees & partners (e.g., frequency of contact, satisfaction with the partnership, types of collaborative clinical research)?	Physical evidence	Progress reports; program documents; PIs, Co-PIs, and partners	Data extraction; semistructured interviews	Descriptive statistics, qualitative analysis	Data quality and reliability	Precise statements about the sample; possible extrapolation to larger universe; anecdotal information
9)	What is the influence of collaboration on clinical research and treatment outcomes at the grantee sites?	Physical and documentary evidence; clinical trial participation rates	Progress reports; program documents; PIs, Co-PIs, and partners	Data extraction; document retrieval; semistructured interviews and questionnaires	Descriptive statistics, qualitative analysis	Data quality and reliability	Precise statements about the sample; anecdotal information
10)	What has contributed to &/or prevented collaboration between grantees & partners (e.g., barriers to collaboration)?	Physical and testimonial evidence	Progress reports; PIs, Co-PIs, and partners	Data extraction; semistructured interviews	Descriptive statistics, qualitative analysis	Data quality and reliability	Precise statements about the sample; possible extrapolation to larger universe; anecdotal information
Evaluation Question #4: What is the influence of TELESYNERGY® on building partnerships, facilitating clinical research, and improving treatment outcomes?							
11)	What has been the experience of grantees & partners with TELESYNERGY® (e.g., influence on clinical research and treatment outcomes facilitated collaboration)?	Quantitative documentary and testimonial evidence	Progress reports; program documents; PIs, Co-PIs, grantee staff, and partners	Data extraction; semistructured interviews; structured questionnaires	Descriptive statistics, qualitative analysis	Data quality and reliability	Precise statements about the sample; possible extrapolation to larger universe

	Key Questions (s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Limitations	What the Analysis Will Allow You to Say
Evaluation Question #5: Has Patient Navigation facilitated access to cancer care and improvement of patient outcomes in the target populations? Has Patient Navigation improved/facilitated participation of minorities in clinical trials?							
12)	Has Patient Navigation facilitated participation of minorities in clinical trials, improved access to cancer care services, and impacted patient outcomes?	Quantitative documentary and testimonial evidence	Progress reports; program documents; PIs, Co-PIs, Patient Navigators, and patients	Document retrieval; data extraction; semistructured interviews; focus groups	Descriptive statistics, qualitative analysis	Data quality and reliability	Precise statements about the sample; possible extrapolation to larger universe; anecdotal information